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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/509,196	03/23/00	DALY R	1871-129

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EXAMINER	
CHERNYSHEV,O	

ART UNIT	PAPER NUMBER
1646	18

DATE MAILED: 04/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/509,196	DALY ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) 8-18 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 23 March 2000 is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 1-18 are pending in the instant application.

Applicant's election with traverse of restriction requirement in Paper No. 8 is acknowledged. The traversal is on the ground(s) that claims of the Groups I and V are drawn to polynucleotide sequences that have a relation to one another. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups are independent or distinct for the reasons in the previous Office action (see Paper #7). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed 20 December, 2000 (Paper #7) Applicant has offered no evidence to rebut this showing. Therefore, a *prima facie* case for a serious search burden was presented in Paper #7 and Applicant has offered no evidence to rebut this showing.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 1-7 are under examination in the instant office action.

Priority

2. The instant application was filed as 371 application of PCT/AU98/00795, filed September 23, 1998. The instant application should contain as the first line of the specification a statement that this application is the national stage entry of PCT/AU98/00795, filed September 23, 1998 as a claim of priority. Correction is required.

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been received in the instant application.

Oath/Declaration

4. It appears that at least one full given name of applicant Robert L. Sutherland is not present in the signature in the papers. This application will not be passed to issue until the omitted name has been supplied or unless a statement has been supplied over the applicant's signature setting forth that the name as signed is the actual full name of applicant Robert L. Sutherland. See MPEP § 605.04.

Drawings

5. The drawings filed on 03/23/00 are subject to correction of the informalities indicated on the attached "Notice of Draftperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required.

6. The figures of the instant application are presented on separate pages or in separate panels. 37 C.F.R. § 1.84(u) (1) states that when partial views of a drawing which are intended to

form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. For example, the three pages of Figure 1 in the instant specification should be renumbered "Figure 1A" – "Figure 1C" rather than "Figure 1". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, Figure 1 is divided into Figures 1A-1C, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner. Correction is required.

Specification

7. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

8. Lines 19-25 of page 8 of the specification are impossible to read due to the small font and poor quality of the copy. A substitute page is suggested.

Also, due to the poor quality of text print in the PTO copy of the application (for example, most of the commas in the text appear as periods, which make it difficult to understand the specification), a substitute specification may be in order.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated polynucleotide molecule encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The polynucleotide of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a

patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to a DNA and the protein encoded thereby of as yet undetermined function or biological significance. It is clear from the instant application that the protein described thereby is a candidate effector protein, currently designated 2.2412, for the Grb7 family of signaling proteins. "The Grb7 family represents a family of SH2 domain-containing adaptors" (page 2, lines 7-8 of the specification). It has been suggested in the specification that "Grb7 family proteins exhibit differential expression in certain human cancers (particularly breast and prostate cancer) and may therefore be involved in tumour progression. Detection of the protein encoded by the cDNA 2.2412 in a sample should provide a useful tumour marker and prognostic indicator for these cancers. Furthermore, the interaction of Grb7 family members with 2.2412 may provide a novel target for therapeutic intervention" (page 5, lines 13-19) (emphasis added by the Examiner). However, in the absence of knowledge of the biological significance of this specific DNA and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. It is asserted in the instant application and in certain publications, quoted by Applicant, that the gene products of Grb7 family of signaling proteins are correlated with human breast cancer. Based on this assertion, a novel interacting protein 2.2412, which is a candidate effector protein for the Grb7 proteins was cloned and characterized. The belief that a claimed novel protein is candidate effector protein for the Grb7 proteins, which maybe associated with cancer, does not make the instant DNA or encoded protein diagnostic of cancer . There is no evidence of record which associates the instant DNA or encoded protein with any human cancers. To employ the DNA and the protein in the future methods for of treating tumor progression or for therapeutic intervention is not a real

world because it would eventually relate to a protein for which no biological function is known. The instant application also fails to demonstrate use of the protein as a marker for any type of cancer (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, one cannot diagnose, prevent or treat cancer or any other condition or disease as implied by the specification. To employ a DNA of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

10. Claims 1-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

12. Claims 1-3 are directed to polynucleotides which have 75%, 85% and 95% sequence identity to the polynucleotide having SEQ ID NO:1. However, the instant specification fails to describe polynucleotides, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a polynucleotide molecule which has sequence of SEQ ID NO:1. The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are polynucleotides having 75%, 85% and 95% sequence identity to the polynucleotide having SEQ ID NO:1. First, the claims are not limited to a polynucleotide with a specific nucleic acid sequence. The claims only require the polynucleotide share some degree of structural similarity to the isolated polynucleotide of SEQ ID NO:1. The specification only describes a polynucleotide having the nucleic acid sequence of SEQ ID NO:1 and fails to teach or describe any other polynucleotides which lacks the nucleic acid sequence of SEQ ID NO:1 and has the activities possessed by the claimed isolated protein. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polynucleotide of SEQ ID NO:1. The specification does not provide a complete structure of those polynucleotides which have 75%, 85% and 95% sequence identity to the polynucleotide having SEQ ID NO:1. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those polynucleotides which have 75%, 85% and 95% sequence identity to the polynucleotide having SEQ ID NO:1.) because the specification teaches only the one embodiment of SEQ ID NO:1. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claims 2-5 recite the limitation "a polynucleotide molecule". There is insufficient antecedent basis for this limitation in the claim. This ground of rejection could be avoided if recitation "the polynucleotide molecule" is used.

15. Claim 4 is indefinite for reciting a nucleotide sequence which substantially corresponds to that shown as SEQ ID NO:1. It is not clear want the metes and bounds of substantially are.

16. Claim 6 recites the limitation "a host cell". There is insufficient antecedent basis for this limitation in the claim. This ground of rejection could be avoided if recitation "the host cell" is used.

Conclusion

17. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *OC*
March 31, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud